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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,358	03/04/2002	David Tumey	VAC.702.US	3855

7590

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EXAMINER

TRUONG, LINH T

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

5

Office Action Summary	Application No. 10/090,358	Applicant(s) TUMEY, DAVID	
	Examiner Linh Truong	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/24/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed on 7 January 2005 have been fully considered but they are not persuasive. Per applicant's arguments for claims 1-10, the examiner respectfully disagrees:

Applicant argues that there is no motivation for the combinations of Henley, Hibner, and Overton. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Henley comprise a canister connected to a vacuum line and Hibner comprise a canister connected to a vacuum line and a sensor and although Overton does not include a canister connected to a vacuum line, Overton comprises a gas chromatograph for sensing microorganisms in fluids, which applicant claims as the inventive aspect of the present invention. The Examiner would also like to point out that the applicant references Overton et al. in the specification as having a "...detection device that may be utilized to detect the presence, concentration, and/or type of infection present in the wound site...."[0018].

Per applicant's argument that Hibner teaches away from what is taught in the present invention by filtering fluids before the sensor, the examiner respectfully traverses. Although the sensor in Hibner is placed after a filter, the examiner would like to point out that the 'filter' of Hibner is a strainer used to "...prevent the passage of fragmented tissue portions through it and into fluid collection system (col. 10, lines 26-29). Tissue fragments may include **some** microorganisms but not **all** microorganisms, thus microorganisms well also be collected in the fluid collection system. Thus, applicant's argument that no useful data will be collected is moot.

The rejections for claims 1-10 below are maintained for the reasons discussed above.

Claim Rejections -35 USC ~ 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5- 6, and 10, are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley et al. (Henley) '6,458,109 in view Hibner et al. (Hibner) '6,120,462 and in further view of Overton et al. '5,611,846.

For claims 1-3, 5- 6, and 10, Henley teaches a wound treatment apparatus with a bandage assembly that includes a drainage bandage 20 (screen means) that contacts

the wound and a delivery bandage 18 that seals the drainage bandage 20 and the wound site (col. 5, lines 11-17), a vacuum source fluidically communicating with the drainage bandage 20 via flexible tube 24, a sensing device (172 or 174) and a collection canister (164 or 166). Henley does not expressly teach that the sensing device is placed between the screen means and the vacuum source nor does he expressly teach that the collection canister is placed between the screen means and the sensing device. Pressure sensors are commonly known in the art for sensing if there is too little vacuum pressure or too much vacuum pressure. Hibner teaches a fluid collection system with a main vacuum line 328 that attaches canister 318 to a vacuum pump 330 with a pressure sensor 328 interposed between the canister 318 and the vacuum pump 330 (fig. 14 and col. 15, lines 51-63). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the invention of Henley with the same line connections of the canister, sensor, and vacuum source of Hibner for sensing pressure more accurately.

Henley and Hibner do not teach that the sensing device comprises a gas chromatograph comprising of a photo diode. Gas chromatographs are commonly used in the art to identify the contents of gaseous samples. Overton et al. teaches a portable gas chromatograph comprising a photoionization (which contains a photo diode) detector (col. 12, lines 23-26). Therefore it is obvious to one with ordinary skill in the art at the time the invention was made to substitute the sensor of Hibner for the gas chromatograph of Overton et al. in order to detect microorganisms/infection in the drainage fluids.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henley et al. (Henley) '6,458,109 in view Hibner et al. (Hibner) '6,120,462 in view of Overton et al. '5,611,846 and in further view of Lewis et al. '6,017,440.

For claim 4, Henley, Hibner, and Overton et al. do not teach that the sensing device comprises a sensor array. Lewis et al. teach sensor arrays for detecting microorganisms/infection. Therefore it is obvious to one with ordinary skill in the art at the time the invention was made to substitute the sensor of Hibner for the sensor array of Lewis et al. in order to detect microorganisms/infection in the drainage fluids.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henley et al. (Henley) '6,458,109 in view of Hibner et al. (Hibner) '6,120,462 and in view of Overton et al. '5,611,846 and in further view of Scherson et al. '5,855,570.

For claim 7, Henley, Hibner, and Overton et al. do not disclose a dressing (screen means) that is embedded with a sensing device for detecting infections. Scherson et al. teaches an oxygen- producing bandage with several layers, wherein one of the layers comprise a sensor (col. 4, lines 31-39). Therefore it is obvious to one with ordinary skill in the art at the time the invention was made to provide the invention of Henley, Hibner, and Overton et al. with a dressing embedded with a sensor in order to detect the infections at the wound area.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henley et al. (Henley) '6,458,109 in view of Hibner et al. (Hibner) '6,120,462 and in view of Overton et al. '5,611,846 and in further view of Fleischmann '6,398,767.

For claim 8, Henley, Hibner, and Overton et al. do not teach that the sensing device senses infections and is disposed on the sealing means. Fleischmann teaches a wound treatment apparatus that comprises a sealing means 14 and a sensing device 38 that is disposed on the sealing means 14 and is in contact with a screen means 12 (fig. 1 and col. 4, lines 62-64). Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to provide the sealing means of Henley, Hibner, and Overton et al. with a sensing device to detect infections in the atmosphere near the wound area.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henley et al. (Henley) '6,458,109 in view of Hibner et al. (Hibner) '6,120,462 and in view of Overton et al. '5,611,846 and in further view of Parker et al. '4,955,391.

For claim 9, Henley, Hibner, and Overton et al. disclose a canister and a sensing device outside of the canister but does not disclose a sensing device for sensing infections located in the canister. It is well known in the art that canisters are used as collection devices for fluids, and, thus, the fluids can be assessed. Parker et al. teaches a fluid monitoring apparatus comprising a canister 22 with a sensing probe 64 mounted inside the canister (col. 5, lines 16-21). Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to provide the invention of Henley, Hibner, and Overton et al. with the sensing probe of Parker et al. to modify the location of the sensing device from being placed outside of the canister to being placed within the canister (as taught by Parker) for more accurate sensing of infections within the canister.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Linh Truong whose telephone number is 571-272-4938. The examiner can normally be reached on Mondays to Fridays from 10am-4pm.

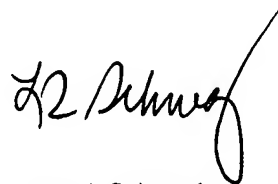
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Schwartz can be reached on 571-272-4390. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Linh Truong

L.T.



Larry I. Schwartz
Supervisory Patent Examiner
Group 3700